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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,870

08/18/2003

James N. Chmura

7111US01

3672

25755 7590 05/18/2007
ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
DEPARTMENT 108140-DS/1
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EXAMINER

PRATT, HELEN F

ART UNIT

PAPER NUMBER

1761

MAIL DATE

DELIVERY MODE

05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/642,870	Applicant(s) CHMURA ET AL.	
	Examiner Helen F. Pratt	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite in the use of the phrase "having a calcium to lipid weight ratio". Part A of claim 1 does not require any amount of lipid in the composition since it recites "up to". Therefore, a particular calcium to fat ratio would not be possible.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 8, 11-19, 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lien et al. (2004/0062849 A1) in view of Thomas (6,313,273) and Rangavajhyala et al. and Lasekan (US 2004/0062820 A1) and Quinlan et al. (applicants' reference).

Lien et al. disclose a nutritional formula, which contains isolated soy protein with a phytate content of 100 MG/liter or less (abstract). The reference discloses a nutrition formula for infants with various amounts of lipids, carbohydrates (CHO), soy protein and calcium (page 3, 0035). Claim 1 differs from the reference in the particular amounts of ingredients, and in the amount of phytic acid and in the particular calcium to

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lipid weight ratio. However, Thomas et al. disclose that it is known how to make a high quality soy protein concentrate (SPC) using enzymes and diafiltration. The reference discloses that the phytate impurity is removed by filtration (col. 25, lines 37-55).

Rangavajhyala et al. disclose that an infant formula with amounts at within the claimed ranges is known (col. 9, lines 5-15). Lasekan et al. disclose that it is known to administer a source of calcium and fat to enhance bone mineralization (abstract). The claimed ratio of calcium to fat is seen to have been shown as the claimed amounts of ingredients have been disclosed (page 7, 0069 (Table VI)). Also, Quinlan et al. disclose that there is a relationship between calcium and fatty acid soaps in formula fed infants. The reference discloses that it is the calcium associated with soaps that imparts the strong correlation with stool type and solids content (page 89, col. 1. and abstract). Therefore, it would have been obvious to use phytase treated soy protein and amounts within the claimed ranges and a particular ratio as disclosed by the combined references in the composition of Lien et al.

Particular amounts of ingredients are seen to have been within the skill of the ordinary worker to vary. The discovery of an optimum value of a result effective variable is ordinarily within the skill of the art. In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). In developing an infant formula, properties such as reduction of phytic acid and calcium to lipid ratio are important. It appears that the precise ingredients as well as their proportions affect the reduction of phytate and the effect of the composition on an infants stools, and thus are result effective variables which one of ordinary skill in the art would routinely optimize.

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The limitations of claims 11-19 have been disclosed above, and are seen to be obvious variations, which have been disclosed above and are obvious for those reasons.

Claim 22 further requires feeding an infant the claimed formula, which is seen as an obvious use of the claimed infant formula.

Claims 23-27 further require feeding the claimed infant formula in order to soften infant stools and relieve constipation, and to provide nutrition. However, the reference to Quinlan et al. in particularly disclose that there is a connection between fat and calcium that affects constipation and stool hardness in infants as disclosed above. Therefore, it would have been obvious to give infants the formula of the combined references, which due to the low level of phytates and the ratio of calcium and fat as disclosed by the references would relieve these conditions.

Claims 9, 10, 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above combined references as applied to the above claims, and further in view of Simell (EP 0380343), and Han (J. Agric. Food chem., pages 259-262), Applicants' references).

Claims 9 and 20 further require that the soy protein be prepared by a particular method. The fact that the procedures of the reference are different than that of applicant is not a sufficient reason for allowing the product-by-process claims since the patentability of such claims is based upon the product formed and not the method by which it was produced. See *In re Thorpe* 227 USPQ 964. The burden is upon applicant to submit objective evidence to support their position as to the product-by-process

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claims. See Ex parte Jungfer 18 USPQ 2D 1796. The reference to Thomas et al. disclose that the soy protein is diluted and then diafiltered (abstract). Diafiltering with water would have preformed the same function as washing with water, since the phytates are removed. Also, Simell et al. disclose that it is known to wash soy protein after the protein was treated with a phytase (FINASE S, TRADEMARK) (page 8, lines 35-50. The reference discloses that a large portion of the seed phytate is water-soluble and is easily extracted by water (page 262, 1st paragraph). Therefore, it would have been obvious to make a soy protein treated with phytase, which has been further washed and to use it in the composition of the combined references.

Claims 10 and 21 further require that the phytase treated soy protein is washed until only a particular amount of phytic acid is in the soy protein. Simell discloses that 0.6 % phytic acid can be produced with further washing. No patentable distinction is seen in 0.3% and 0.6% at this time. In addition, the method of removing the phytic acid is not given weight in a composition claim. Therefore, it would have been obvious to remove any residual phytic acid by washing particularly as disclosed by Han that some of the phytic acid can be water-soluble.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hp 5-16-07


HELEN PRATT
PRIMARY EXAMINER